JUN - 8 2004

K044041

SHANGHAI FOREMOST PLASTIC INDUSTRIAL CO., LTD.
Yan Li River Bridge East, Che Xing Highway, Che Dun Town,
Songjiang County, Shanghai,201611, PRC
TEL: 86 21 5760-9473 FAX: 86 21 5760-9245 E-mail: shaforemost@online.sh.cn

510 (k) Summary

As Required by 21 section 807.92 (c)

1. **Submitter Name:** Shanghai Foremost Plastic Industrial Co. ,Ltd.
2. **Address:** Yan Li River Bridge East, Che Xing Highway, Che Dun Town, Songjiang County, Shanghai,201611, PRC
3. **Phone:** (+86) 21 5760-9473
4. **Fax:** (+86) 21 5760-9245
5. **Contract Person:** Chaiyos Sincharoenkul (General Manager)
6. **Date summary prepared: December 10, 2002**
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 30798 US Hwy. 19N Palm Harbor, USA , FL 34684
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E Harris
12. **Device Trade or Proprietary Name:** Powder free Vinyl Examination
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Glove , Patient Examination , Vinyl
15. **Substantial Equivalency is claimed against the following device :**
    Shanghai Foremost Vinyl Patient Examination Glove, Powder free, 510(k) #k971415 (refer to Appendix 1 for FDA website printout)
    This notification for the Powder free Vinyl Examination glove is of the ABBREVIATED type as per the declaration of conformity on page B2 of this summary
16. **Description of the Device:**
    Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder free Vinyl Patient Examination Glove, 80LYZ, and meets all requirements of ASTM Standard D5250-00 ^{E4}
17. **Intended use of the device:**
    This device is a disposable device intended for medical purpose that is worn on the examiner 's hand to prevent contamination between patient and examiner
18. **Safety and effectiveness of the device:**
    This device is safe and effective as the predicate device *Shanghai Foremost Vinyl Patient Examination Glove, Powder free*. Indeed, it is equivalent
    This is better expressed in the tabulated comparison (Paragraph 19 below)

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19. Summary comparing technological characteristics with other predicate device: General comparison result between Powder free Vinyl Examination and predicate device (***Shanghai Foremost Vinyl Patient Examination Glove, Powder free***) is tabulated below.

Technical comparison of specific elements is attached in the main submission.

FDA file reference number	510k Number: K971415
Attachments inside notification submission file	REFER TO APPENDIX 1
TECHNOLOGICAL CHARACTERISTICS	***Comparison result*** **REFER TO ADDITIONAL TECHNICAL COMPARATIVE TABLE WITHIN 510K SUBMISSION**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (Not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shanghai Foremost Plastic Industrial Co., Ltd.
C/O Mr. Ned Devine
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548-1289

Re: K041041
Trade/Device Name: Non-Sterile Synthetic Powder Free (Yellow) Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: May 26, 2004
Received: May 28, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

Applicant: **Shanghai Foremost Plastic Industrial Co., Ltd.**

510(k) Number: K041041

Device Name: Non Sterile Synthetic Powder Free (Yellow) Vinyl Patient Examination Gloves

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041041